Summary of the Quality Systems Committee Teleconference September 29, 1997

The Quality Systems Committee of the National Environmental Laboratory Accreditation Conference (NELAC) convened by teleconference on September 29, 1997, at 1 p.m Eastern Standard Time. The meeting was led by its chair, Ms. Sylvia Labie of Florida's Department of Environmental Protection. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of this meeting was to discuss comments received on the Quality Systems chapter*.

INTERIM MEETING

Tentatively scheduled to be held in Washington, DC, the week of December 2, 1997.

NEW MEMBERS

The committee welcomed two new members; Mr. Ray Frederici and Mr. Ciff Glowacki. Mr. Frederici and Mr. Glowacki introduced themselves, providing some background and their objectives for the Quality Systems committee.

Names, address information corrections:

Mr. Glowacki should be CIH rather than CIN.

New fax for Ms. Sheila Meyers -6307 and mailcode 176.

Mr. Scott Sider's phone number should be changed to 785-5163.

COMMENTS

1. North Dakota

Comments received from North Dakota apply to the glossary. The glossary soon will be taken out of Chapter 5, so these comments can be addressed later. "Uncertainty" was found in four places, suggesting that the definition may be needed. The term may be applicable to calibration labs rather than testing labs. Committee Decision: The term "uncertainty" will be removed from the "general" discussion (strike from 5.10.2). In 5.13, item 12 includes the word, but it is already modified by the phrase "where relevant."

2. EMMC

Dr. Fred Haeberer has a single paragraph saying the elements of the Quality Systems chapter are default requirements and that a customer may ask for more- or less-demanding controls. Mr. Siders suggested that some organizations may be looking for general loopholes, but the Quality Systems committee has raised the minimum requirements. From State accrediting

authority standpoint, laboratories can be more stringent, as stringent, or less stringent than NELAC standards. This allowance for less stringent opens a loophole that could be abused.

<u>In the absence of specific guidance from a program or client (perhaps part of a QA Project Plan that justifies the lessened controls)</u>, the laboratory must satisfy the NELAC requirements.

3. Ms. Joan Fisk's comments

Three of the four comments from Ms. Fisk dealt with the above item. Ms. Fisk's comment III deals with renumbering 5.9.4.3. The Committee tabled discussion at this time.

4. EMMC comments

The Committee reviewed the comments from the Dallas meeting to be sure none were overlooked and none were found. A related comment from New York: in 5.1.B change "regulations" to "EPA Regulations."

<u>Editorial</u>: At the end of Section 5.1b insert "(See the limitations of supplemental accreditation requirements in section 1.9.2)" inside the period of the last sentence (just before item c).

A recommendation was made that EMMC should have consensus among Program Offices before they bring suggestions before the Quality Systems committee. Comments from individuals do not necessarily represent the Agency-as-a-whole.

5. Department of Defense Comments

These written comments were addressed:

- 1. 4.1.1.1 does exist.
- 2. "Proprietary rights" needs to be added
- 3. All the possible performance tests do not need to be discussed.
- 4. 5.5.4.c add "(see 5.11.2, Sample Acceptance Policy.)"
- 5. While Class S weights are no longer marketed, many are still in use and the name is commonly recognized. Change "has not" to "have not."
- 6. Delete first sentence? Is it redundant? Rationale (adds no value) is unclear. No change.
- 7. New item f) "Samples which show signs of damage or contamination."
- 8. Storage conditions are adequately covered under 5.11.4.a.1? Add "contamination" in first sentence of 5.11.4 and add phrase "including highly contaminated samples" at end of 5.1..4.a.2.
- 9. Section 5.11.5 Delete last phrase ("including all ...laboratory")
- 10. Section 5.12.2.b becomes "All records, including those specified in 5.12.3 and 5.12.4, shall be retained for a minimum of five years. All information necessary for the historical reconstruction of data must be maintained by the laboratory. Records which are only stored on electronic media must be supported by the hardware and software needed for their retrieval."

- 11. 5.13.a has already been corrected.
- 12. We can not specify font size.
- 13. Compromised sample was deleted.
- 14/15. MDL issue will require effort in the future. Action Item: in letter to EPA, request Agency consensus on MDL issues.
- 6. Dr. Ken Jackson's comments have already been addressed.

NEXT MEETING

Next conference call will be October 6 from 2-4 p.m. Eastern Standard Time. During the call, the committee will continue working through the large packet of comments. (Comments by Cliff Kirchmer, Matt Caruso, James Pearson, Jeff Flowers, Ken Inn, Advanced Systems, and Scott Siders.)

The call following that will be October 22 from 10-12 a.m.

ACTION ITEMS Quality Systems Committee September 29, 1997

Item No.	Action	Date Completed
1.	RTI to make changes to Chapter 5, as discussed in the 9/30/97 conference call.	9/30/97
2.	RTI to provide minutes of 9/29 conference call.	9/29/97
3.	Mr. Haeberer will draft a paragraphs discussing how customers may require levels of control that are less stringent (or more stringent) than NELAC. He'll distribute copies to committee members.	10/6/97
4.	Mr. Slayton will draft a letter to EMMC requesting consensus among Program Offices before comments are forwarded to NELAC. The letter will also include a request that the Agency provide some consensus guidance on detection limits.	10/6/97

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